

V. A. Carroll

23 Scenic Drive, Merewether NSW 2291
(PO Box 1078, Newcastle NSW 2300)
Phone (02) 4963.3761 Fax (02) 4963.3761

12 June 2012

The TGA Labelling and Packaging Review
PO Box 100
Woden ACT 2606

Re: TGA Medicine Labelling and Packaging Review

Dear Sir,

You will note from a number of attachments to this submission that I have been personally involved in the campaign to improve the labelling of prescription medicines since the early 1980's.

I strongly agree with every one of the proposals listed in the Consultation Paper (dated May 2012) as many of them are along the lines that I proposed, decades ago, as a director of the Pharmacy Guild of Australia and as a community Pharmacist.

The only variations that I would suggest are...

- 1. That the name of the active ingredient should be in "bold" typeface significantly larger than the brand name.***
- 2. That the answer to the question: "What is the smallest size font that you consider readable?" should give due consideration to the advanced age, and failing eyesight of the large number of elderly consumers.***

Finally, from my experience, I have found that the manufacturing lobby does, at times, appear to neglect to place the need for patient safety above that of their commercial and marketing priorities.

As a result I urge the TGA to consider the needs of patient safety as having the absolute right of precedence.

Yours sincerely,

A handwritten signature in black ink, appearing to read "V. A. Carroll".

V A Carroll MPS PhC (Retired)

LETTERS

The trade name game

Time for a non-proliferation treaty on confusing trade names

Dear editor,

In my younger years, I wrote numerous articles and letters, some of which were critical of the pharmacy establishment, in Guild publications and letters to pharmacy trade press. My criticisms of the Guild were such that I was finally forced to "put up or shut up" and much to my surprise, I was elected as NSW Guild vice president and eventually a national councillor.

A number of my articles, written while a Guild vice president, were disapproving of various drug manufacturers' policies of corporate labelling and inadequate packaging — which I believe, many years later, still create a significant risk to patient safety. At the time this didn't win me any friends in the drug industry.

Unfortunately I have observed that the longstanding problem of petite corporate packaging with insufficient space for the pharmacist's label and other essential information is still alive and well.

Since my retirement from the Guild and from active pharmacy I have refrained, up until now, from commenting on current pharmacy matters.

However, as an interested observer I am dismayed at the incredibly folly of the PBS proliferation of generic "trade names".

Perhaps my own advancing years are a factor, and I am concerned that I may become a victim of medication trade name misadventure in my dotage.

This proliferation causes widespread confusion among patients, medicos and pharmacists, and can only become worse with the forecast increase in existing generic use, together with the number of widely prescribed drugs losing patent protection in the relatively near future.

And with the Free Trade Agreement, we might end up with 20 or 30 trade names for one generic.

Patients are often switched to the preferred generic brand in each pharmacy they visit and are confused not just by the change in size, colour and shape of the medication but also the changes in name and style of packaging.

Medicos are confused as they don't recognise many of the generic drug's trade names in discussion with patients.

Likewise, pharmacists have difficulty recognising trade names which are not in use in their own pharmacies.

Do we really need multiple trade names such as Alphamox, Amohexal, Bgramin, Cilamox, Moxacin, Amoxil and Maxamox for amoxicillin? What's wrong with using "amoxicillin (AF)" or (BG) or whatever? Wherever did they dig up Bgramin? And why do we need dozens of trade names ending in "--hexal"?

And then there's Lovan, Prozac, Auscap, Fluohexal and Zactin for fluoxetine — how ludicrous is this?

Pick any popular out-of-patent drug,

listed in the Schedule and marvel at the imagination of the marketing gurus.

I know I'm not alone in believing that patient welfare should be the primary consideration of all stakeholders acting within the PBS. Does anyone genuinely believe that this confusing complexity of trade names is of any benefit to patients?

The solution seems simple — but nothing is ever simple in our world of the ever-expanding bureaucracy.

Fairly obviously, the PBS listing should only allow trade names for innovator brands, and restrict all "me-too" generic PBS listings and package labelling to the generic name, with the manufacturer's name in smaller type. Some ethical generics manufacturers have already come close to embracing this policy.

In an ideal world, lobbying by individual pharmacists, the Guild and the Society would penetrate the politico-bureaucratic maze and raise an awareness that this muddle of unnecessary gobbledegook leads to patient misadventure, greater consumption of health care, unnecessary hospitalisation and increased cost to the public purse.

This is not an ideal world, but hopefully commonsense may yet prevail.

Vic Carroll
Newcastle
NSW

Drug name confusion risking patients' lives

Consumers are exposed to unnecessary danger, writes **Shane Carney**.

ALL manufacturers love to brand their products, and medicines are no exception.

Unfortunately, while consumers also find brand names useful, they are now causing health problems, particularly with the recent proliferation of generic medicines.

Once a prescribed medicine had only two names, its generic (active ingredient) and brand name.

But the rapid increase in generic medicine brand names once a drug is off patent has changed the environment for good.

Consumer confusion because of brand name proliferation is causing double dosing, with the potential for increased drug side effects and even death.

As an example, Amlodipine (innovator brand name Norvasc), a blood pressure lowering drug, is now off patent, with 14 brands now available in Australia.

Some responsible generic companies simply add their name to the generic name such as Amlodipine - Terry White Chemists.

Other names such as Amlodipine, Nordip, Norvapine, Ozlodip and Perivasc bear little relationship to the generic name or the condition it treats.

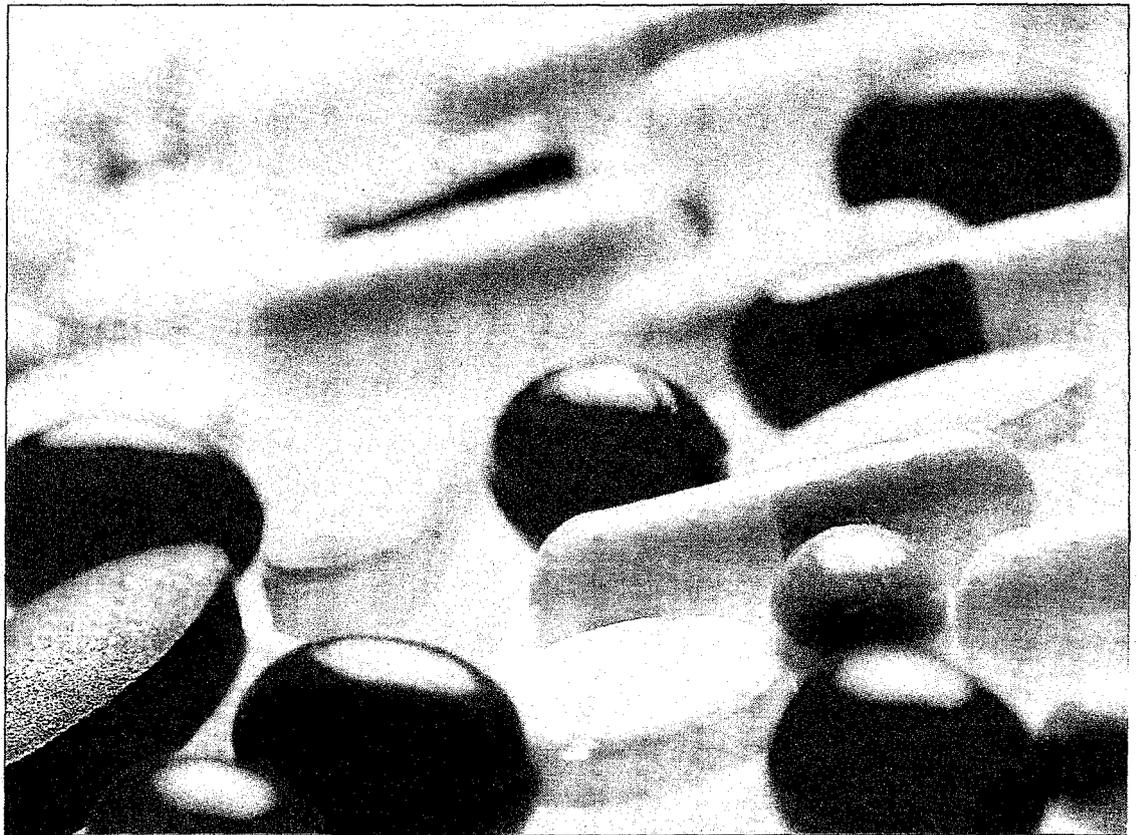
Brand confusion doesn't just occur with prescription medicines. It's just as bad with the medications you buy across the counter at your local pharmacy or supermarket.

Most consumers don't know that the commonly used analgesics, Panadol, Paracetamol and Panamax are the same - Paracetamol.

Furthermore, if you see Duatrol, Dymadol, Febridol, Lemsip and Paralgin at your pharmacy, they are also Paracetamol.

It's not just consumers who are concerned and confused by an almost exponential increase in brand names.

Doctors and pharmacists are particularly concerned about the potential for harm by the presence of thousands of brand names, many of which bear no relationship to anything except the desire by manufacturers to anoint a drug with a cute name.



CARE: As patents on much-used drugs expire, proliferating brand names can lead to accidental overdose.

Companies that bring new and important drugs into the marketplace are not blameless.

According to NPS, an independent, not-for-profit and evidence-based medicines information service, generic medicines now account for about 40 per cent of prescriptions filled on the Pharmaceutical Benefits Scheme.

While they have exacerbated the brand name confusion problem, generic medicines are just as effective as the originals (innovator) drugs.

While health professionals are seeing an increase in inadvertent double dosing because of brand confusion, it's hard to quantify.

Taking two forms of Paracetamol for a headache will not usually lead to harm, although Paracetamol at high dose can be toxic.

Taking a double dose of a prescription medicine, however, can be much more dangerous.

Adverse events from medicines account for more than 190,000 hospital admissions each year in Australia, which can't be ignored.

The first step in solving brand name confusion is to change the Australian medication labelling laws so that the generic name is not only larger than the brand name but also has a distinctive font and colour to facilitate consumer education.

Manufacturers can still use their beloved brand name, although brand names also have other reasons to confuse because the names look and sound alike.

However, brand names do have limited value since they are often easier to pronounce.

Another step you can take is to encourage your pharmacist to stock the same brand to minimise confusion.

The Therapeutic Goods Administration has set up a labelling committee which will

include public consultation early next year.

Another initiative available soon that should minimise brand name confusion is a personally controlled electronic health record being developed by the National E-Health Transition Authority. This electronic record will include a medication list composed of all prescribed (and dispensed) medications.

You will also be able to add your own over-the-counter medications as well as complementary medications.

If you ever have concerns about the medications you are taking, always talk to your doctor or pharmacist.

Shane Carney is an associate professor of medicine at Newcastle University and a consultant nephrologist at John Hunter Hospital.



Guild LINES

Vol.25. No.5.
March 14, 1985.

This article by Vic Carroll, Vice President, is the second in a series by Committee Members.

Corporate or Inadequate Ethical Packaging (Or why the L.O.L. took the wrong tablets)

For many years official pharmacy bodies have been concerned about the real, and potential, error rate, both by pharmacists and patients, occasioned by the similarity or inadequacy of ethical packaging of drugs with vastly different therapeutic actions.

There is no argument that the final responsibility to dispense the correct product lies with the pharmacist. However, it must be the responsibility of every link in the pharmaceutical-supply chain, to ensure that risk to the patient is not increased by their policies.

Some companies have taken positive action to correct their problem packaging. However, others are reluctant to incur the considerable costs involved, for a number of reasons. The most obvious being the financial restrictions imposed by the Commonwealth Health Department. At the moment such costs would almost certainly not be recovered by compensating NHS price adjustments.

It is reasonable to assume that a proportion of patient compliance misadventures may be associated with problem packaging. As the number of hospital admissions, due to iatrogenic (drug induced) diseases is quite high in the elderly, there is little doubt that such packaging is part of the cause.

Consider the 75 year old, with amongst other medications, her thyroid, heart and blood pressure tablets, all small and white and all in the same shape, colour and size containers with the same coloured lid. To compound the problem all items are labelled "as directed". (That's another area of concern).

Is it really surprising that she is admitted to hospital suffering from over digitalisation or some other drug induced condition?

Hospitals are not immune from this problem. A recent fatal case involving a number of hospitalised infants, was caused in part by "two products having almost identical labels on identical bottles".

In 1979 The National Working Party on Packaging and Labelling consisting of representatives from Government and all areas of Pharmacy, Hospitals and Industry, made a number of positive recommendations, some of which were:

1. No less than 70mm X 50mm should be available for the pharmacist's label.
2. The product name, storage conditions, expiry date and batch number should be positioned so as not to be obscured by the pharmacist's label.
3. Manufacturers' labels should not normally contain information on dosage.

Continued on page 3.



MEETINGS FOR GUILD MEMBERS

WOLLONGONG
Monday, March 18

*Convention Room,
Normandie Motor Inn,
30 Bourke Street,
Wollongong
Commences at 8.00pm*

NOWRA
Tuesday, March 19

*Rendezvous Room,
Parkhaven Lodge,
Cnr. Kinghorn and Douglas Streets,
Nowra*

*Commences at 8.00pm
preceded by dinner at 7.00pm*

BEGA
Wednesday, March 20

*Conference Room,
Bega RSL Club,
158 Auckland Street,
Bega*

*Commences at 8.00pm
preceded by dinner at 7.00pm*

LEURA
Monday, March 25

*Fitzroy Room,
Leura Gardens Motor Inn,
Fitzroy Street,
Leura*

*Commences at 8.15pm
preceded by dinner at 7.00pm*

All our members are warmly invited to attend the meeting in any of the areas.

The President, Peter Webeck, will be accompanied to each meeting by members of the Branch Committee and a representative of Guild Insurance.

These meetings are an opportunity for information exchange on areas of interest and concern to pharmacy and to discuss potential problems and possible solutions. Your participation is welcomed.

Please phone Mrs Joan Loerch at the Guild on (02) 438 3333 to confirm your attendance at any of the above meetings.



Guild Bulletin

Issued by The Pharmacy Guild of Australia (NSW Branch), Guild House, 79 Lithgow St., St. Leonards 2065. Ph 438 3333 Vol.28. No.24. 2nd Sept. 1988

YOUR REQUEST

For better labelling and packaging of prescription medicines . . .

Frustration is probably the best word to describe the feelings of both pharmacists and consumers in their ongoing battle for improved packaging and labelling of prescription medicines. Years of negotiations with the Government for stricter regulations to control the standards of packaging and labelling have achieved little and many pharmaceutical manufacturers stubbornly continue their romance with microscopic packs and much loved "corporate image" packaging. Below, Pharmacy Guild of Australia (NSW Branch) Vice-President Vic Carroll reviews the progress made to date in this area and offers some tactics all pharmacists can use in working towards a solution to this problem which is adversely affecting our professionalism.

The problem

Two main areas of concern can be identified where pharmaceutical packages for dispensing products are deficient:

◆ **Size of packages**

A large percentage of original manufacturers' pack dispensing consists of packages that are so small it is impossible not to cover part of information such as name, strength, batch number and expiry date, with the pharmacist's dispensing label.

◆ **Similarity of packages**

Corporate (similar appearance) packaging for a range of products which may vary widely in strength or indications is a common occurrence.

The solution

In 1979, a National Working Party on Packaging and Labelling which was made up of representatives from Government and all areas of pharmacy (including the Pharmacy Guild), put forward a number of positive recommendations to overcome this problem. They included:

- (a) Packs should have a total area of not less than 70 mm x 50 mm available for the pharmacist's label,
- (b) The following essential data should be positioned on the manufacturer's label in such a way as to facilitate the pharmacist's label without obscuring any of the following information.
 - (i) the product details; and
 - (ii) storage conditions, expiry date and batch number, which should be placed close together.

The Working Party considered that labelling should be designed to meet the needs of the users, i.e., pharmacists and patients, and that bureaucratic designs should not be imposed.

However, these were only recommendations and as such cannot be legally enforced. Sadly, this has meant that very little change has occurred in manufacturers' attitudes to packaging and labelling.

The manufacturers' attitude

Some progress has occurred and those manufacturers who have "their act together" are to be congratulated.

However, many manufacturers continue their romance with microscopic packs and much loved "corporate image" packaging. Many are still using the excuse that their overseas principals are not interested.

It was hoped that the level of drug recalls that have occurred due to confusing packaging and labelling would have caused manufacturers to rethink their overall concepts in this area.

The obvious risk to public safety and the enormous cost in dollar and reputation terms that these recalls cause, should result in any company practising "corporate image" packaging, to change direction in the interests of survival.



Vic Carroll

If problem packaging is to be upgraded only when such recalls occur, then it is likely that there will be many more such disasters before we have a semblance of sanity in the design of prescription packaging. It is strange that the cost of public liability insurance hasn't forced all manufacturers into the era of safe "patient friendly" designs and packages.

However, requests for voluntary changes of particular packages often receive the response that such changes are expensive and require long lead-in times. Yet it is amazing how quickly a redesigned pack can appear when there is an economic motivation, such as an increased NHS maximum quantity or the need for a new "market image".

The pharmacists' dilemma

As a result of recent actions by the Federal Consumer Affairs Bureau, national advertising to the public of recalls of suspect prescription medicines must now include those medicines already dispensed.

This creates quite a dilemma for pharmacists.

The advertisements are now asking consumers to check the name, strength, batch number and expiry date of their dispensed medication. This gives rise to the concern over how patients are supposed to check such vital information when the pharmacist's label has been affixed over at least part of these essential details.

As a large percentage of original manufacturers' pack dispensing consists of packages where it is impossible not to cover at least part of such information with the pharmacist's label, pharmacists usually have to make the choice between complying with State law and NHS regulations or running foul of consumer legislation. Therefore both the pharmacist and the public are victims of conflicting bureaucratic demands.

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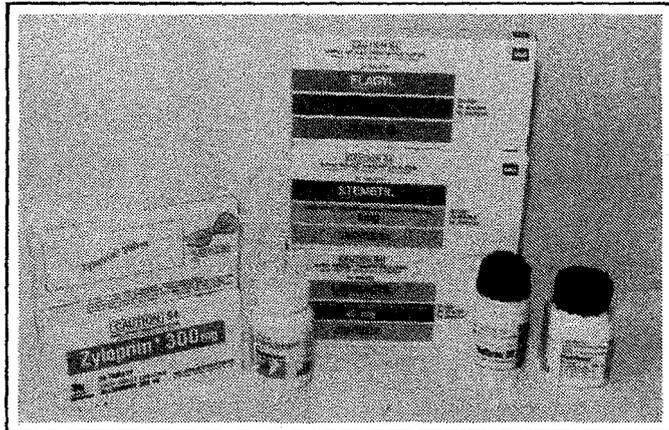
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Guild Bulletin

Issued by The Pharmacy Guild of Australia (NSW Branch), Guild House, 79 Lithgow St., St. Leonards 2065. Ph 438 3333 Vol.27, No.6, Mar 27 1987



Here is a sample of products whose manufacturers have recently altered packages to minimise potential difficulties.

For many years and during the past year in particular, pharmacists and official pharmacy bodies have been concerned about the potential and actual dangers to members of the public occasioned by the inadequacy of the packaging and labelling of some drugs. A significant proportion of patient compliance disasters and iatrogenic (drug-induced) diseases can be traced directly to problem packaging. The problem is particularly serious amongst the elderly who are more prone to confuse their medication. Take for example, a 75 year old patient whose thyroid, heart and blood pressure tablets are all small and white and all stored in containers of the same shape, colour and size. Is it really surprising that the patient is admitted to hospital suffering from over digitalization or some other iatrogenic condition?

The Combined Pensioners' Association and the Australian Consumers' Association have formed a working committee (the Guild has accepted the invitation to have a representative on this committee) and a survey is presently being carried out among elderly patients to investigate any difficulties they may have with their medication. While the Guild has had no part in the development of this survey, we await the results with interest.

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INADEQUATE PACKAGING

Patient care
or corporate image



by Vic Carroll
Vice President,
Pharmacy Guild of Australia
(NSW Branch)

The size of some packages also poses difficulties. As anyone practising the profession of pharmacy knows, the law requires the pharmacist to appropriately label the medication as part of dispensing procedures. In addition, recent legislation requires the pharmacist to place another label on the container if the substance has any side effects likely to impair driving or the operation of machinery.

At present, many containers are simply too small and it may be physically impossible to comply with the law in affixing these labels without obscuring other relevant information appearing on the container.

While pharmacists applaud such legislation in the interests of improved patient care, the packaging must change to be in harmony with these labelling requirements.

As long ago as 1979, a National Working Party on packaging and labelling consisting of representatives from Government and all areas of pharmacy, hospitals and industry produced guidelines for packaging and labelling. Among these guidelines were the following recommendations:

1. No less than 70mm x 50mm should be available for the pharmacist's label.
2. The product name, storage conditions, expiry date and batch number should be positioned so as not to be obscured by the pharmacist's label.
3. Manufacturers' labels should not normally contain information on dosage.

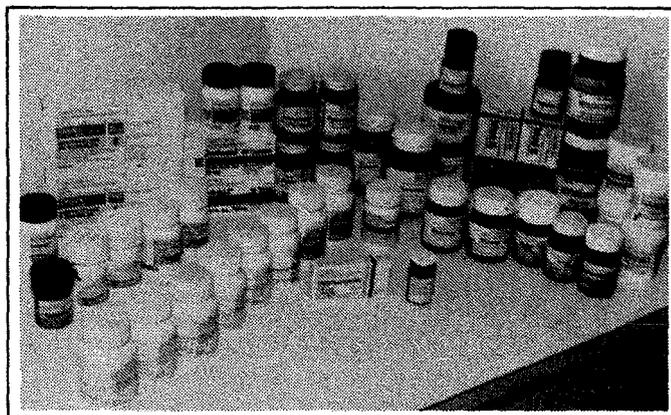
4. Labelling should be designed to meet the needs of the users, (i.e. patients and pharmacists) and that corporate designs should not be imposed at the cost of this.

Clearly, it must be the responsibility of every link in the pharmaceutical supply chain to ensure that patient care comes first and is not compromised by the quest for "corporate image".

The Guild wrote to the Australian Pharmaceutical Manufacturers' Association on this issue and, upon their advice, has written to the specific manufacturers whose packaging is considered inadequate.

A number of manufacturers have shown their concern about this issue and have promptly changed their packaging (e.g. by changing colours) to minimise such difficulties as the possibility of confusing one package with another. We applaud the efforts of these companies.

On the other hand, a number have been slow to remedy the difficulties associated with their packaging. Members may wish to take up any such difficulties with the representatives from those companies where potential misadventures are perceived. In some cases, members have reported discussions with their local medicos about the potential compromising of patient care in the prescribing of these products.



Here is a sample of products which are perceived to present potential difficulties and we await the manufacturers' action.

A NATIONAL COUNCILLOR'S PERSPECTIVE

During 1990 NSW Guild members will see a major change in the composition of a state branch committee, which has had the same membership for the past six years. This report will be, in fact, a summary of my involvement in the six year life of that committee.

During the first four years I held the positions of Vice President and Chairman of the Health Services Sub-Committee followed by, during the last two years, the role of National Councillor.

Our first task was to accept that, although we had been elected mainly on a National Health platform, the Guild's involvement encompassed a far broader range of issues. It was, at first, somewhat deflating to realise that PBS matters are decided at a higher level than state branch committees and that we had to get on with the job of addressing the myriad of other important matters that impact upon community pharmacy.

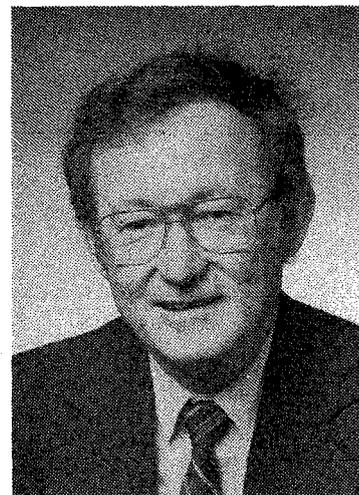
PACKAGING

As many members will recall our Sub-Committee has been waging a campaign for the upgrading of ethical packaging to an acceptable standard. Over the six years many packages have improved, but much more remains to be achieved. It is disappointing that some manufacturers as well as some arms of government are not taking more positive action to achieve the obvious benefits to consumer health and safety, which would flow from the adoption of these improved standards. The battle will continue.

AIDS

Back in 1985 our Branch recommended to members that they should supply sterile needles and syringes to suspected intravenous drug users. This was to be followed by an exchange program as soon as practicable. At the time this was a revolutionary concept and, initially, met with the disapproval of many members of our profession, the public, many in authority and wide sections of the media.

However, in time, this initiative of our Branch was recognised by the World Health Organisation as the most effective, proven program for containing the spread of HIV infection amongst the IV drug using community. As the IV drug users are recognised as the group most at risk of infecting the general population, there is no doubt that this program has had significant and immeasurable benefits for our society. If our committee had achieved nothing else, this one initiative would be enough.



Vic Carroll

EDUCATION

Our present Health Services Chairman, Robert Taylor has been involved in pharmacy education and the upgrading of the university curriculum to encompass greater clinical involvement. Discussion has commenced with Newcastle University regarding a future pharmacy school, hopefully, to provide more graduates who will be prepared to spend their professional lives outside the metropolitan environment. The present difficulties with the PBS have unfortunately relegated this project to the back burner.

JULY '93

LETTERS

Inertia affects 'inadequate' labels

Editor,
THE present debate about barcoding of pharmaceutical packaging is rather intriguing and has the potential to continue for some time.

Years after the food giants coerced the food manufacturers into universally barcoding their products, our "Working Party" indicates that it believes that a 3 to 6 year (further) time span is reasonable.

In 1987 it was suggested that the guild recommend to members that a higher retail margin should apply to non bar-coded products on the basis that such products are more expensive to handle than those which are barcoded.

This may not have achieved the desired re-

sult as expeditiously as in the food industry, but it would have been extremely unlikely that in 1993 we would still be looking at a further 3 to 5 years for implementation.

When criticised for this non-decision, the "Working Party" has leapt to the defence of the indefensible by stating...

"Many packages are very small and are already overcrowded with information required by law..."

Comment. They're telling us? They should try finding room for a dispensing label.

"Manufacturers must be persuaded that there is an economic benefit to be derived before committing themselves to

such an investment..."

Comment. What about patient care? and a final ripper...

"The Pharmacy Guild has been asked by these companies to **explain** how the code would be used, when presently much of the information displayed on the package is being obscured by a pharmacy generated label."

(Read it again !!!!!)

Comment. The Pharmacy Guild should have no difficulty in again explaining the problems associated with these precious little packages.

All the offending manufacturers have been advised, many times since 1979, that their packages are inadequate for dispensing purposes.

This response has a fa-

miliar ring, as the APMA has previously excused their inertia by stating that ... "a particular problem exists with prescription pharmaceuticals as finding room for a barcode on very small and already crowded packaging is just one problem faced by APMA and PMAA members"

What is the agenda of this "Working Party"?

What is its composition?

Does it include any practising Community Pharmacists (who actually have to use these packages)?

How representative of Community Pharmacy or consumers is this "Working Party"?

What has it achieved?

For the information of this "Working Party", a

previous, more representative Working Party, consisting of representatives of the Government, Pharmacy, consumers and manufacturers, back in 1979, made recommendations regarding "ethical" packaging which required, amongst other guidelines, that a 50mm x 70mm space should be provided for the dispensing label, so that other information (batch numbers, expiry dates etc) need not be covered.

Had the manufacturers complied with their own recommendations during the past 14 years, they would now have more than sufficient room for barcodes on their packaging.

Over the years Community Pharmacists

have been regularly criticised by everyone from the BIE (Bureau of Industrial Economics) at their 1984 hearing up to this current "Working Party", for obscuring information with "pharmacy generated labels".

It would be interesting to see our critics attaching "pharmacy generated labels" (as required by law) to some of the inadequate packaging provided by "ethical" companies.

Strangely, some of the packaging from the much maligned generic manufacturers is more patient and pharmacist friendly than much of that produced by our "ethical" manufacturers.

Could this be part of

the reason for the increased acceptance of "generics" by community pharmacy?

Now that pharmacists have a more influential role in the selection of prescribed brands, is there a message here, for some manufacturers?

A well packaged, generic Norethisterone 5 mg (Primolut N) for example, would corner the market overnight.

The inescapable truth is that much ethical packaging is totally inadequate for its intended role as a dispensed product, so it naturally follows that it is inadequate for barcoding.

**Vic Carroll
Kurri Kurri Pharmacy
NSW**

Resize the type

There is a very simple solution to the confusion caused to patients by repeated changes in the brand names of generic drugs and that is for all drugs to have the generic name for all drugs in large bold print on the medication label and then the brand name in smaller print below it. Thus, in the case of Lipitor, the generic name "atorvastatin" would appear in large bold print and "Lipitor" would appear below it in smaller print.

This is what happens in Britain and for all medications prescribed by hospital pharmacies. It is supported by the medical profession, but the pharmaceutical industry opposes it as it would reduce brand recognition and hence profits for the pharmaceutical industry.

It is high time that the government put the interests of patients before the interests of big pharma and legislated for all medications to be labelled generically.

Dr Ian Arthur Toormina